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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,668	10/14/2003	Steve Mitchell	KLYCD-05008US1	3396

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/684,668	Applicant(s) MITCHELL, STEVE	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-16, 18, 19, 21 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-16, 18-19, 21, 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed March 30, 2005, have been fully considered.

Regarding the rejections under 35 U.S.C. 112, second paragraph, applicant's has cancelled claims 17, 20, and 22. The Examiner believes that claim 23 is incorrect; the socket of the lower plate is parallel to the sagittal plane as shown in figure 1G not perpendicular as claimed.

Regarding the rejection of claims 1, 4-12, 14, 21-23, 35-36 under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0106998), applicant's has submitted a declaration to overcome the rejection. The declaration filed on 3/30/05 under 37 CFR 1.131 has been considered but is ineffective to overcome the Ferree reference. The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Ferree reference. For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development; the submitted drawings do not prove the device was built and tested.

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070), applicant states that referring to the embodiment shown in figures 38 and 42-49, the device does "***not allow for continuous, selective bending of the vertebrae bodies to undergo flexion, extension, and/or lateral bending.***" The Examiner notes that applicant does not use the limitation "continuous" in every

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independent claim or the other limitations such as flexion, extension, etc. Referring to claim 35, applicant has amended the claim "such that the implant allows continuous selective movement of the vertebral bodies". It is the Examiners position that at least the device shown in figure 42 could be continuously adjusted via crossbar beams 740 and 760, even further, the first and second piece are not fastened together; there is no reason why the two pieces (plates) could not be continuously separated from each in extension. Applicant's broadest claims 39 and 40 were not amended. Applicant provided no arguments as to these claims are allowable over Wagner et al.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

As previously stated, "*Applicant uses many different terms to describe the upper and lower plates including first piece, second piece, first member, second member. All claim language must be supported in the specification.*" It is applicant's duty to assure all claim language is supported in the specification; please direct to the specification for support for:

Claim 1, first piece and second piece;

Claims 1, first piece is capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending.

Claim 21, upper implant and lower implant.

Claim 29, first spacer member and second spacer member.

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These are examples only.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, first piece is capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending.

Similar for claim 21, the limitation is broader than the specification.

Claim Rejections - 35 USC § 112, Second Paragraph

Claim 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 23, the claimed configuration is ambiguous. The socket of the lower plate is parallel to the sagittal as shown in figure 1G not parallel.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, 9-14, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Yarrow (4,499,613).

Yarrow teaches an implant comprising a first piece 24 having a first socket , a second piece including 16 having a second socket 66, 68 and a crossbar member 44 that is at least partially received in the first socket and the second socket.

See first bar 46 and second bar 62.

Claim 19, a foot in the art is sometimes referred to as a keel.

Claims 1, 4-6, 9-12, 14, 21-23, 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0106998).

Note that the provisional application No. 60/416,181 was filed on October 4, 2002 and supports figures 1-6 only. Ferree teaches an implant comprising a first piece 104 having a first socket a second piece 104' having a second socket and a crossbar member 102 that is at least partially received in the first socket and the second socket.

The crossbar member includes first and second bars configured perpendicular forming a "T" or "+" shape.

Regarding claim 5, the socket or interior surfaces comprise many different slopes.

Claims 1-6, 9-23 and 26-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070).

Applicant must consider all configurations taught by Wager, a couple configurations are specifically discussed. Referring to figures 8-9, Wagner et al teaches an implant comprising a first piece 12 having a first socket 60, a second piece 14 having a second socket 60 and a crossbar member 30 that is at least partially received in the first socket and the second socket.

Regarding claim 2 having first and second bars that are perpendicular, see figure 6B showing element 30 having generally "I" shape having upper and lower bars

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separated by a middle bar. **Also see figures 42-49 wherein the spacer (crossbar) includes at least elements 740, 760 and the cam block. All other elements are self-evident. See the embodiments shown in figure 38 wherein the bars abut.**

Claims 3 and 26, inherently the "I" shape has a bar above the middle bar. Also, referring to figure 9, another interpretation the first bar 30 is mounted higher or above second bar 32.

Regarding claim 12, see at least figure 42.

Regarding at least claims 15-20 claiming a keel, see at least elements 516, 616, 716, 816, 916, 1016.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (2004/0106998) in view of Marnay (WO 01/01893).

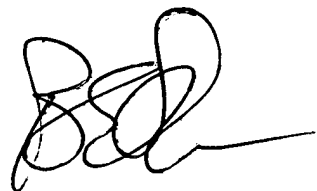
Ferree teaches the implant as described above, however, fails to teach a keel. Marnay teaches the keel configuration as claimed. It would have been obvious to one having ordinary skill in the to have used the keel/s of Marnay on the implant of Ferree to better anchor it to the vertebrae.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER